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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Plaintiffs, v. AMBU A/S, AMBU INC., AMBU LTD., AMBU SDN. BHD., Defendants. AND RELATED COUNTERCLAIMS	Case No. 3:07-cv-01988 DMS-NLS **DECLARATION OF DR. SAMSUN LAMPOTANG IN SUPPORT OF DEFENDANTS' RESPONSIVE CLAIM CONSTRUCTION BRIEF**

I, Dr. Samsun Lampotang, declare as follows:

1. I am a Professor of Anesthesiology at the Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida. I submit this Declaration in support of Defendants' Responsive Claim Construction Brief. I have personal knowledge of the facts stated in this Declaration, and, if called as a witness, I could and would testify competently to those facts and to my expressed opinions.

2. I have read The Laryngeal Mask Company, Ltd.'s and LMA North America, Inc.'s (collectively, "LMA" or "Plaintiffs") Opening Claim Construction Brief ("Plaintiffs' Opening Brief"), as well as the materials submitted by LMA in support of Plaintiffs' Opening Brief. My opinions below are intended to respond to issues raised by those materials.

I. REINFORCEMENT OF THE DISTAL REGION OF THE POSTERIOR CUFF WALL

3. In Plaintiffs' Opening Brief, LMA raises a number of issues concerning the construction of this claim limitation. Specifically, LMA contends that (i) the location of the reinforcement need not be further defined, as it allegedly is clear from the claim language, yet also asserts that "distal region" should be construed to mean "the region of the cuff at the end most distant from the person inserting the device," (ii) the reinforced portion of the cuff wall need not be "thicker and stiffer" than the remaining portions of the cuff, and (iii) the reinforcement of the cuff need not be an extension of the backplate. I will address each of these contentions in turn.

A. Location of the Reinforced Cuff – Distal Region

4. With respect to location of the reinforcement of the cuff, claim 1 states that such reinforcement can be found in "the posterior portion of a wall of the cuff in the distal region." [Ex. C,[1] claim 1.] Based on the nature of the problem that the '100 patent seeks to solve, the specification and the figures therein, as well as in light of the cited prior art and prosecution history, a person of ordinary skill in the art would understand "the posterior portion of a wall of the cuff in the distal region" to mean the part of the cuff between the most distal point of the

[1] References to Exhibits A-R refer to the exhibits attached to my opening declaration.

backplate, exclusive of the backplate extension, and the most distal point of the cuff.

1. The Specification and Figures

5. The opening paragraph of the section entitled "Summary of the Invention" provides guidance on this issue. Specifically, it states that the reinforcement of the cuff is "achieved by incorporating into the cuff at its distal end a reinforcing rib which serves to stiffen the leading end of the LMA-device." [*Id.* at col. 1, lns. 52-54 (emphasis added).] The following paragraph, which states that the "reinforcing rib [is] incorporated into the distal end of the inflatable cuff," further confirms that "the present invention" entails reinforcing the cuff at its "distal end" or "leading end." [*Id.* at col. 1, lns. 61-63 (emphasis added).] Indeed, the specification of the '100 patent uses the terms "distal region," "distal end," and "leading end" interchangeably.[2] From these statements, alone, a person of ordinary skill in the art would understand "the wall of the cuff in the distal region" to mean the part of the cuff between the most distal point of the backplate, exclusive of the backplate extension, and the most distal point of the cuff.

6. The remainder of the specification and figures further confirm the location of the reinforced cuff. The specification, for example, states that "[i]n the installed position of FIGS. 1 and 2, the projecting but blunted distal region 60 of the main-cuff is shaped to conform with the base of the hypo-pharnyx." [*Id.* at col. 4, lns. 64-66.] As shown below, the distal region, identified by 60, is the region of the cuff from the tip of the backplate to the tip of the cuff.

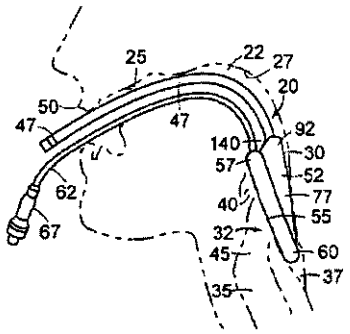


FIG. 2

[2] Eliminating any doubt that these terms are used interchangeably, the specification states that the "distal region 60 of the fully deflated main-cuff 55 is the leading end of the LMA-device." [*Id.* at col. 8, lns. 39-40.]

The language quoted above also describes the distal region of the cuff as "projecting," meaning that the cuff juts out from the tip of the backplate. Indeed, there is no structure other than the tip of the backplate from which the distal region of the cuff could project.

7. The following excerpts from the specification further confirm that the "distal region" is the part of the cuff that protrudes from the tip of the backplate:

> When the backplate 52 is attached to the main-cuff 55, the distal rib 105 pierces the proximal surface of the distal region 60. The edges of the main-cuff 55 in the distal region 60 surrounding the distal rib 105 are hermetically sealed to it such that the enclosure of the main-cuff is defined in part by the distal rib. The distal rib 105 extends through the interior of the main-cuff 55 to the distal surface of the distal region 60. [*Id.* at col. 6, lns. 26-33.]
>
> *
>
> FIG. 10 shows a second embodiment of the backplate 52a. Parts in FIG. 10 having corresponding parts in FIGS. 5 and 6 have the same reference numeral with the addition of suffix a. The backplate 52a is similar to the backplate 52 illustrated in FIGS. 5 and 6 except that the distal rib 105a of the backplate 52a is applied to the posterior surface of the distal region 60a of the main-cuff 55a, as shown in FIG. 10. The distal rib 105a has a concave anterior surface corresponding to the adjoining convex posterior surface of the distal region 60a thereby limiting the radial clearance between the distal region and end 60a, 105a. The distal rib 105a does not pierce the posterior surface of the distal region 60a, in contrast to the embodiment shown in FIG. 5, and is therefore separated from the interior of the main-cuff 55a. The distal rib 105a may be effectively constituted by a thickening of the posterior wall of the distal region 60a of the inflatable main-cuff 55a and, as shown, forms a distal extension of the bowl 90a of the backplate 52a. The distal rib 105a has a downturned profile by being incorporated into the posterior surface of the main-cuff 55a. The distal end of the distal rib 105a is spatulate. [*Id.* at col. 7, ln. 62-col. 8, ln. 15.]

These excerpts, and the associated figures (below), make clear that the reinforcement of the cuff occurs in the region of the cuff beyond the tip (excluding the extension) of backplate. As shown in the figures below, given that the reinforcement is achieved by extending the backplate to the tip of the cuff, the distal region necessarily must be that region of the cuff between the tip of the cuff and the tip of the backplate, exclusive of the extension.

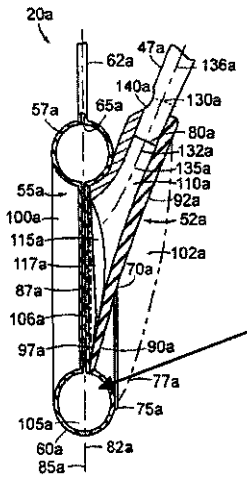


FIG. 10

Reinforcement of the cuff is achieved by extending the tip of the backplate into or over the cuff, thus demonstrating that "distal region" is that region between the tips of the backplate and cuff

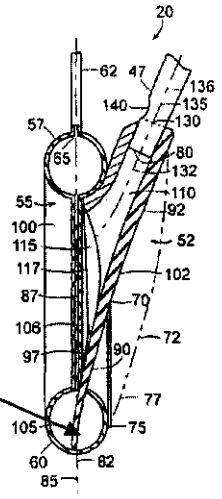


FIG. 5

8. Based on the above, it is my opinion that a person of ordinary skill in the art would understand the "distal region" of the cuff to mean the region of the cuff between the tip of the backplate to the tip of the cuff or, put differently, the region of the cuff distal to the tip of the backplate, i.e. the leading edge of the cuff.

2. The Problem Solved by the '100 Patent

9. My understanding of the meaning of "distal region" is also confirmed by the problem that the '100 patent aims to solve. As the opening sentence in the "Summary of the Invention" states, "[t]he present invention seeks to eliminate the disadvantages associated with such undesirable insertion by minimizing the risk of the deflated cuff formation becoming folding over on itself during the insertion procedure." [*Id.* at col. 1, lns. 48-51.] As the next sentence unequivocally states, the '100 patent solves this problem "by incorporating into the cuff at its distal end a reinforcing rib which serves to stiffen the leading end of the LMA-device during the course of the procedure for its insertion." [*Id.* at col. 2, lns. 51-55.]

10. The folding over of the cuff occurs when the leading (distal) tip of the cuff gets caught on some obstruction (for example, tissue in the throat) during insertion of the device. When the cuff folds back, the crease of the fold occurs at the tip of backplate, as the backplate is sufficiently stiff not to fold back, thus causing the cuff to fold over the tip of the backplate. As such, the '100 patent aims to prevent such fold over by reinforcing the portion of the cuff that

folds over the backplate – that is, the region of the cuff between the tip of the backplate and the tip of the cuff. The '100 patent teaches solving the problem through an extension of the backplate, as that approach helps to ensure that the cuff cannot fold over the backplate.

3. The Cited Prior Art and Prosecution History

11. LMA's proposed construction of "distal region" cannot be reconciled with the cited prior art and prosecution history. Specifically, during the prosecution of the '100 patent, the USPTO rejected numerous claims aimed at reinforcement of the cuff. Those rejections were based on U.S. Patent Nos. 6,240,922 ("the '922 patent") and 5,983,897 ("the '897 patent"), as well as European Patent Application No. 0732116 ("the '116 application").

12. In the Office Action dated February 26, 2001, the USPTO rejected the submitted claims on the ground that they were obvious in light of the '897 patent and U.S. Patent No. 5,355,879 ("the '879 patent"). [Ex. H, pp. 4-7.] As is relevant to the present claims, the examiner noted that the '897 patent teaches a laryngeal mask comprising an inflatable cuff bonded to a backplate, including a tube joint that defines the passageway of the backplate, and a rib protruding from the distal tip of the cuff. [*Id.* at 4-6.] The examiner noted that although the reinforcement of the cuff of the '897 patent and the submitted claims were not identical, the modification of the submitted claims was "a mere rearrangement of parts and would have been obvious to one of ordinary skill in the art as an alternate arrangement unless a new and unexpected result is achieved." [*Id.* at 6.]

13. Later, in an Office Action dated October 17, 2005, the USPTO rejected the submitted claims on the ground that they were obvious in light of the '922 patent and '116 application. [Ex. I, pp. 3-5.] In rejecting the claims, the examiner noted that the '116 application teaches a laryngeal mask comprising an inflatable cuff bonded to a backplate that includes a passageway. [*Id.* at 2-3.] Although the '116 application did not disclose a rib as the means of reinforcing the backplate, the examiner noted that the '922 patent did teach a rib, and further stated that "[i]t would have been obvious to one of ordinary skill in the art to modify the backplate of Pagan '116 to employ a longitudinal distal rib doing so would provide support for the cuff." [*Id.* at 3.] The examiner further stated that the rearrangement of the reinforcement of

the cuff "would have been an obvious matter of design consideration." [*Id.* at 3-4.]

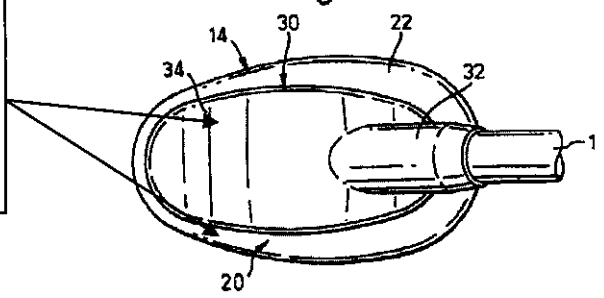
14. As discussed in pages 6-8 of my opening declaration, the location of the reinforcement of the cuff, as claimed by the '100 patent, must be located in the region of the cuff distal to the backplate in order to be distinguishable from the '897 patent and '116 application. That discussion highlights a large problem with LMA's proposed construction, as the '116 application and '897 patent teach laryngeal masks that include the claimed features of the '100 patent, if interpreted as LMA proposes. Further confirming this fact, I have attached hereto as **Appendix A** a claim chart showing that the '100 patent would improperly read on the devices disclosed in the '116 application, if construed as LMA argues.

15. I have been asked to consider whether reinforcing the cuff by thickening and stiffening the cuff wall, as opposed to extending the backplate over or through the cuff, would be a sufficiently distinguishing feature of the '100 patent in order to make it non-obvious in light of the '897 patent and '116 application. It is my opinion that such a rearrangement of the reinforcement would have been obvious to a person of ordinary skill in the art.

16. The prosecution history of the '100 patent shows that the USPTO agreed with my opinion. For example, as noted above, in the very first office action, the examiner rejected claim 4, which claimed a rib within the cuff, on the ground that it is was "a mere rearrangement of parts and would have been obvious to one of ordinary skill in the art as an alternate arrangement unless a new and unexpected result is achieved." [Ex. H, p. 6 (emphasis added).] If LMA's proposed construction were adopted, thus not limiting the reinforcement of the cuff to that region distal to the tip of the backplate, the examiner's comment would be equally applicable to the issued version of claim 1, as the only distinction between the reinforcement of the cuff of that claim and the '116 application would be that the reinforcement was rearranged to be incorporated into the cuff wall, as opposed to sitting on top of the cuff. Figure 3 of the '116 application, below, will assist to illustrate this point. As shown in the figure, the reinforcement of the cuff is achieved by extending the backplate over the distal half of the cuff.

The location of the reinforcement of the '116 application is the same as proposed by LMA for the location of the reinforcement of the '100 patent

Fig.3.



Pursuant to LMA's proposed construction, the reinforcement of the cuff of claim 1 of the '100 patent could be identical, except that the reinforcement would be integrated into the cuff, rather than just sitting on top of the cuff.

17. My opinion is further supported by the examiner's comment in the summary of the in-person interview held on May 22, 2006. Specifically, the examiner noted that the patentee's representative argued that the claim limitation at issue ("at least a first portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff...") was distinguishable from U.S. Patent No. 6,240,922 ("the '922 patent") "in that the Pagan ['922 patent] does not disclose a rib." [Ex. N, p. 3.] A true and correct copy of U.S. Patent No. 6,240,922 is attached hereto as **Exhibit S**. This comment shows that the examiner had expressed that claim 1 was not patentable over the '922 patent, but the patentee distinguished that art on the ground that the '922 patent did not disclose a "rib." Therefore, the examiner did not find the claim limitation at issue to be sufficiently novel of the prior art merely because the reinforcement was incorporated into the cuff wall, as opposed to running through it or over it.

4. "wall"

18. The use of the term "wall" in the claim language further confirms that the reinforcement of the cuff must be an extension of the backplate. A wall is generally a structure that stands vertical to a set plane. This understanding is supported by the claim language and specification, as the patentee did not refer to the reinforcement of merely the surface of the cuff, which would extend circumferentially around the cuff, but rather to the wall. In this case, the wall of the cuff is that portion that stands vertical to the plane of the bowl/cuff. As such, the

reinforcement of the cuff, which is located in the posterior part of the cuff, must be located at one of the parts of the cuff identified below.

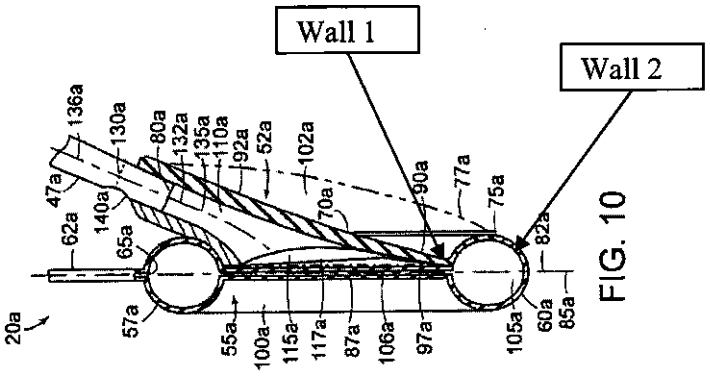


FIG. 10

Given the problem that the invention seeks to solve, folding over of the cuff, the wall referred to in claim 1 must be that identified as "wall 1" above, for if "wall 2" were the reinforced wall, such a design would not prevent the cuff from folding over itself, as the reinforced part of the cuff would fold over the unreinforced portion. The wall of the cuff identified above as "wall 1" is the wall that makes contact with the backplate, thus further demonstrating that the reinforcement of the cuff must be an extension of the backplate.

B. Thicker and Stiffer

19. In Plaintiffs' Opening Brief, LMA asserts that the claim language, stating that "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other potions for the cuff," does not require the "thicker and stiffer" portion to be thicker and stiffer than all other portions of the cuff. LMA's construction is inconsistent with the invention taught by the '100 patent and with how a person of ordinary skill in the art would understand that language.

20. Based on the claim language, alone, a person of ordinary skill in the art would understand that the reinforcement of the cuff is thicker and stiffer than all other portions of the cuff. The language states that the reinforced portion of the cuff is "thicker and stiffer than other portions of the cuff" without limitation. It does not state that the reinforcement is thicker and stiffer than some other portions or substantially all other portions of the cuff. As such, a person of ordinary skill in the art would understand "other portions of the cuff" to mean those portions of

the cuff except for the reinforced portion referred to in the claim language.

21. LMA's proposed construction is also contrary to the well-established purpose of a cuff. The cuff is the part of the laryngeal mask that forms the seal over the laryngeal inlet. Given the variable surface of the tissue in that area, cuffs are designed to be uniformly thin, as taught by the '100 patent, so as to make them as pliable as possible, thus enabling them to mold to the shape of the patient's throat and enabling a tighter seal over the laryngeal inlet. Indeed, a significant goal of the '100 patent's reinforcement of the cuff is to assure that the cuff does not become folded back, "thereby obstructing the creation of the seal around the patient's laryngeal inlet and hence obstructing formation of a full enclosed airway to the patient's lungs." [Ex. C, col. 1, lns. 36-40.] Under LMA's construction, however, portions of the anterior side of the cuff could be thicker and stiffer than the reinforced part of the cuff. Such a construction would run contrary to the purpose of a cuff and even the stated purpose of the invention, as a significant purpose of preventing cuff fold over is to ensure that cuff achieves a complete seal when the device is inserted.

C. Reinforcement of the Cuff as an Extension of the Backplate

22. As stated in my opening declaration, a person of ordinary skill in the art would understand that the reinforcement of the cuff wall, as described in claim 1 of the '100 patent, is an extension of the backplate. Given the specification only describes the construction of the reinforcement of the cuff to be an extension of the backplate, I do not believe that a person of ordinary skill in the art would understand the reinforcement to be anything else but such an extension of the backplate.

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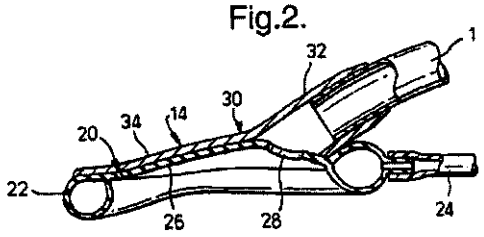
II. BACKPLATE

23. As I stated in my opening declaration, at the time the application leading to the '100 patent was filed, a person of ordinary skill in the art understood a backplate to be separate from an airway tube and would include a tube joint. That meaning has not changed, and persons of ordinary skill in the art still understand the term "backplate" in the same way.

24. The cited prior art of the '100 patent confirms that a backplate is separate from an airway tube and includes a tube joint. The '116 application, for example, teaches a laryngeal mask comprising a "backing member" 34 (i.e. backplate) that extends from sealing member 22 (i.e. cuff) to the airway tube 1. [Ex. F, col. 2, lns. 4-15.] The backplate, in turn, comprises a tube joint, referred to as a "mount member" 30, including a tubular extension 32, that is used to connect the backplate to the airway tube 1. [*Id.* at col. 2, ln. 57 – col. 3, ln. 3.]

Fig.2.



25. The use of the term "backplate" in these materials is consistent with the description of "backplate" in the specification of the '100 patent, as well as Ambu's proposed construction. Specifically, in a device such as Ambu's, which has been lodged with the Court, an airway tube that is extended to the opening of the mask, rather than one that is attached to a tube joint, is not considered to be a "backplate." Rather, as the intrinsic record of the '100 patent makes clear, a backplate is understood to mean a support structure in addition to the airway tube.

III. CUFF BEING ATTACHED TO THE BACKPLATE

26. In Plaintiffs' Opening Brief, LMA asserts that the '100 patent teaches two structures of a laryngeal mask, one wherein the backplate and cuff are part of a single unitary piece and a second structure wherein the backplate, cuff, and airway tube – all separate pieces – are attached together. I agree with LMA that the '100 patent teaches both apparatuses, but I disagree that the language of claim 1 – specifically, "the cuff being attached to the backplate" –

actually claims both forms of the device.

27. As I noted in my opening declaration, the '100 patent expressly teaches the single, unitary piece form of the device as an alternative form of device to that of one wherein the cuff is attached to the backplate. [*See, e.g.*, Ex. C, col. 6, lns. 11-33.] Indeed, after the specification describes the alternative form of device consisting of a single, unitary piece, it proceeds to revert back to discussing the other form and states "[w]hen the backplate is attached to the main-cuff, the distal rib pierces the proximal surface of the distal region." [*Id.* at col. 6, lns. 26-28.] This use of "attached" makes clear that the backplate and cuff were separate pieces that were joined together, particularly given the use of "when," which can leave one only to conclude that prior to when the pieces were attached or joined, they were separate.

28. Further, the first two paragraphs of the "Summary of the Invention" state that the reinforcing rib is "incorporated" into the cuff. [*Id.* at col. 1, lns. 50-63.] When something is "incorporated" into another thing, they were necessarily previously separate. As such, the reinforcing rib, which was incorporated into the cuff, must have been previously separate from the cuff. As further explained in the specification of the '100 patent, that reinforcing rib is an extension of the backplate, which is then incorporated into the cuff when the backplate and cuff are attached. The "Summary of the Invention," therefore, confirms that the backplate and cuff are separate pieces.

IV. DISTAL RIB

29. LMA's proposed construction of "rib" is inconsistent with the use of the term in the specification and the cited prior art. LMA contends that the "distal rib" need not be rib-shaped or narrower than the diameter of the tube joint.[3] With respect to the shape, all of the figures in the '100 patent that show the distal rib portray it as rib-shaped – that is, a generally straight, long and narrow shape from a posterior or anterior viewpoint. [*See* Ex. C, Figs. 3, 4-8, 9, 11.] Nothing in the specification teaches that the distal rib could be shaped any other way, though the specification does teach that the very tip of the distal rib could be spatulate. [*Id.* at col.

[3] LMA also contends that the distal rib need not be an extension of the backplate. That issue was addressed in my opening declaration.

8, lns. 14-15.]

30. The cited prior art also confirms that "rib" refers to something of a long and narrow shape. The '922 patent, for example, teaches a laryngeal mask including "three stiff ribs 31 to 33, or similar members, projecting down from the roof" of the mask. [Ex. S, col. 2, lns. 53-55.] Those ribs are also shown in Fig. 5 below (see 51-53).

Fig.3.

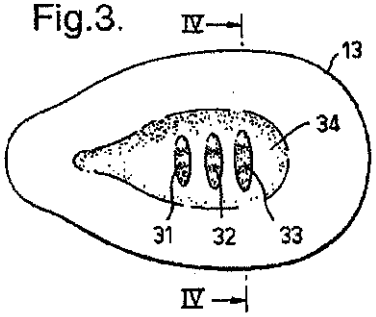
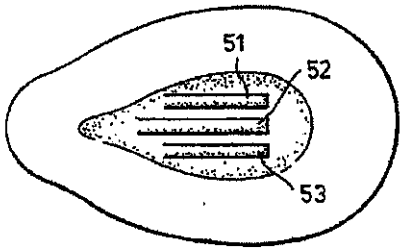


Fig.5.



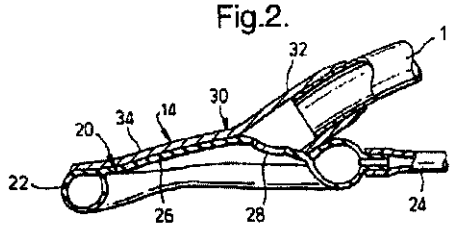
As these figures make clear, the term "rib" was understood by one of ordinary skill in the art to mean a structure that has a long, narrow shape.

31. As to the width of the rib, the patentee distinguished prior art during prosecution by limiting the "rib" of the '100 patent to be narrower than the diameter of the tube joint. [Ex. Q, p. 9.] The patentee's statement in this regard is consistent with all of the figures in the '100 patent that show the rib. Indeed, all of those figures show the rib as being substantially narrower than the diameter of the tube joint.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed this 19th day of December 2008, in Gainesville, Florida.

Samsun Lampotang, ~~Ph.D.~~

Appendix A

Claim 1	Pagan '116
1. A **laryngeal-mask airway device** comprising:	Pagan '116 discloses or renders obvious a laryngeal-mask airway. Pagan '116, Col. 1: 3-6: "This invention relates to laryngeal mask airways of the kind including a mask subassembly and an elongate tube opening at its patient end into the mask subassembly." Pagan '116, Col. 1: 54-55: "According to the present invention there is provided a laryngeal mask assembly of the above-specified kind."
a **backplate** defining a **passage**;	Pagan '116 discloses or renders obvious a backplate defining a passage. This backplate structure is the mask portion of the mask subassembly of which the 'mount member', the 'backing member' and the 'diaphragm' are an integral part, as shown in Figure 2: Fig.2.  Pagan '116, Col. 1: 56-58: "The mask subassembly has a generally planar backing member extending on the rear side of the mask subassembly." Pagan '116, Col. 2: 4-7: "The mask subassembly preferably includes a mount member, the backing member being a part of the mount member and the mount member including a tubular extension attached with the elongate tube." Pagan '116, Col. 2: 4-7: "The mount 30 is completed by a backing plate 34 formed integrally with the tubular extension 32. The backing plate 34 is of generally elliptical shape and extends forwardly from the patient end of the tubular extension."

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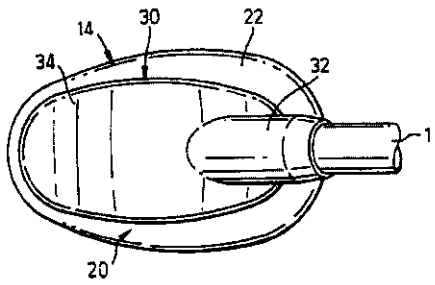
an **inflatable cuff**;	Pagan '116 discloses or renders obvious an inflatable cuff, described as a 'sealing ring'. Pagan '116, Col. 3: 48-51: "The mask subassembly (14) having an inflatable sealing ring (22) located during use in the hypopharynx and opening on its forward side to the patient's airway." Pagan '116, Figure 3: Fig.3. 
the cuff defining a **distal region** and a **central opening** at least when inflated,	Pagan '116 discloses or renders obvious a cuff defining a distal region and central opening. Pagan '116, Col. 2: 42-43: "The mask portion 20 has a peripheral annular sealing ring 22." Pagan '116, Col. 2: 45-46: "The sealing ring 22 is of elliptical shape with its major axis extending in the same plane as the tube." Pagan '116, Figure 3: See above.
the cuff being **attached to the backplate**,	Pagan '116 discloses or renders obvious a cuff being attached to the backplate. Pagan '116, Col. 2: 42-43: "The mask portion 20 has a peripheral annular sealing ring 22." Pagan '116, Col. 2: 42-43: "The sealing ring being a part of the mask portion, the mask portion including a diaphragm extending within the sealing ring and attached to the backing member." Pagan '116, Figure 2: See above. Pagan '116, Figure 3: See above.
the cuff being **insertable through a mouth of a patient** to an **inserted location within the patient**,	Pagan '116 discloses or renders obvious a cuff inserted through the mouth of the patient to a particular location in the airway.

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MOUNTAIN VIEW

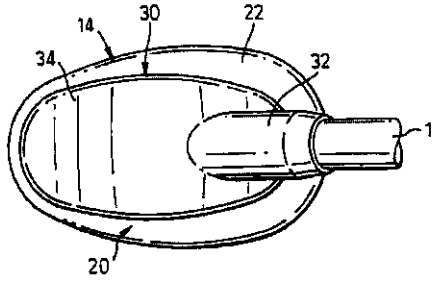
	Pagan '116, Col. 1: 12-15: "The tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue." Pagan '116, Col. 3: 46-51: "A laryngeal mask assembly including a mask subassembly (14) and an elongate tube (1) opening at its patient end into the mask subassembly, the mask subassembly (14) having an inflatable sealing ring (22) located during use in the hypopharynx and opening on its forward side to the patient's airway."
an **airway extending from a laryngeal inlet** of the patient, through the central opening, to the passage when the cuff is inflated and at the inserted location,	Pagan '116 discloses or renders obvious an airway extending from a laryngeal inlet through a central opening to the passage when the cuff is inflated and at the inserted location. Pagan '116, Col. 3: 11-14: "These airways comprise a tube with an inflatable mask or cuff at one end. The tube being inserted in the patient's mouth so that one end is located in the hypopharynx."
at least a portion of the posterior portion of a wall of the cuff in the distal region being **thicker and stiffer** than other portions of the cuff.	Pagan '116 discloses or renders obvious a portion of the posterior part of the cuff in the distal region being thicker and stiffer than other portions. Pagan '116, Col. 3: 8-11: "The lower, forward side of the backing plate 34 is secured to the upper, rear surface of the diaphragm 26 and overlaps the sealing ring 22." Pagan '116, Col. 3: 53-55: "A generally planar backing member (34) extending on the rear side of the mask subassembly to overlap the patient end of the sealing ring (22) such that, when the sealing ring (22) is deflated for insertion, the backing member (34) inhibits rearward deflection of the patient end of the sealing ring." Pagan '116, Figure 3: Fig.3. 

EXHIBIT S

US006240922B1

(12) **United States Patent**
Pagan

(10) **Patent No.: US 6,240,922 B1**
(45) **Date of Patent: Jun. 5, 2001**

(54) **LARYNGEAL MASK ASSEMBLIES**

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(73) Assignee: **Smiths Industries Public Limited Company**, London (GB)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(51) **Int. Cl.**[7] **A61M 16/00**; A61M 16/04

(52) **U.S. Cl.** **128/207.15**; 128/200.26; 128/207.14

(58) **Field of Search** 128/207.15, 207.14, 128/200.26; 604/96, 174

(56) **References Cited**

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5,896,858 * 4/1999 Brain 128/207.15

5,937,860 * 8/1999 Cook 128/207.15

FOREIGN PATENT DOCUMENTS

0 294 200 12/1988 (EP) .
2205499A 12/1988 (GB) .
97/12641 4/1997 (WO) .

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(74) *Attorney, Agent, or Firm*—Pollock, Vande Sande & Amernick

(57) **ABSTRACT**

A laryngeal mask assembly has an elliptical mask portion at the patient end of a tube. The mask portion has a mount attached to the tube and a cuff extending around the periphery of the mount. The patient end of the tube opens into the center of the mount, which has three lateral ribs projecting forwardly and extending parallel and spaced from one another. The forward end of the ribs have a concave profile with rounded projections at each end. The ribs act to hold the epiglottis away from the tube opening during insertion of the assembly and to provide an air passage into the tube.

11 Claims, 2 Drawing Sheets

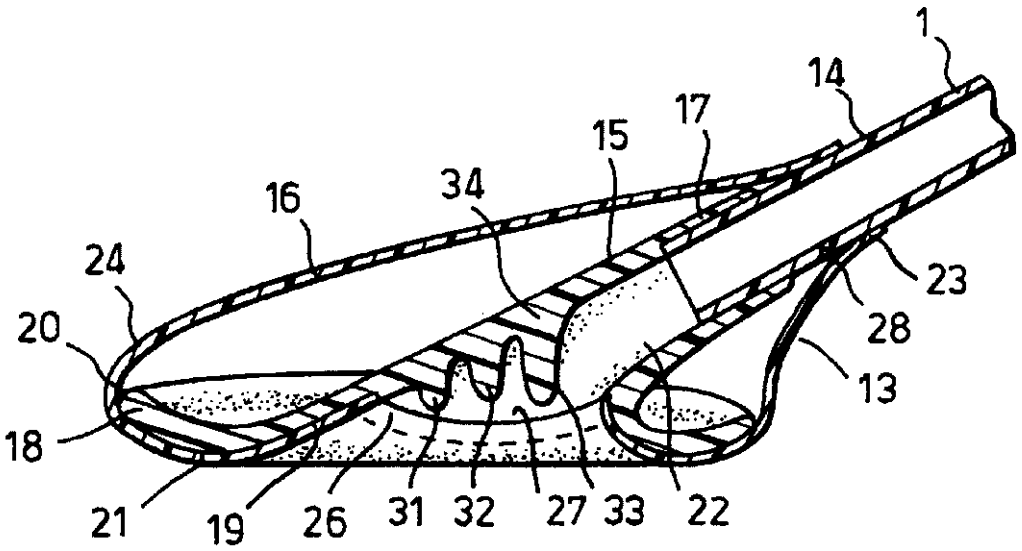


Fig.1.

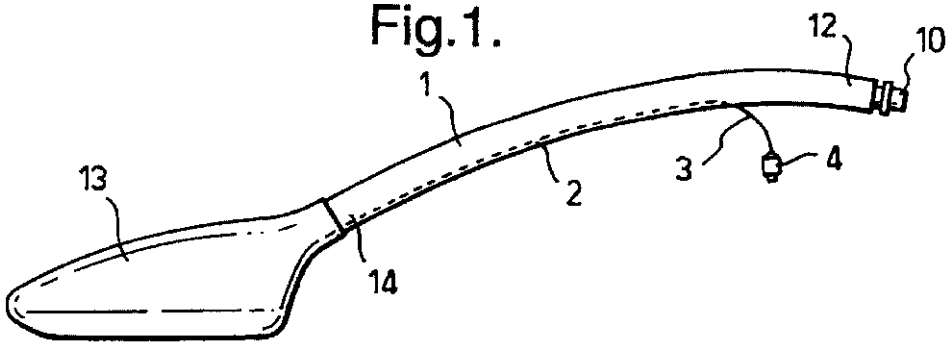


Fig.2.

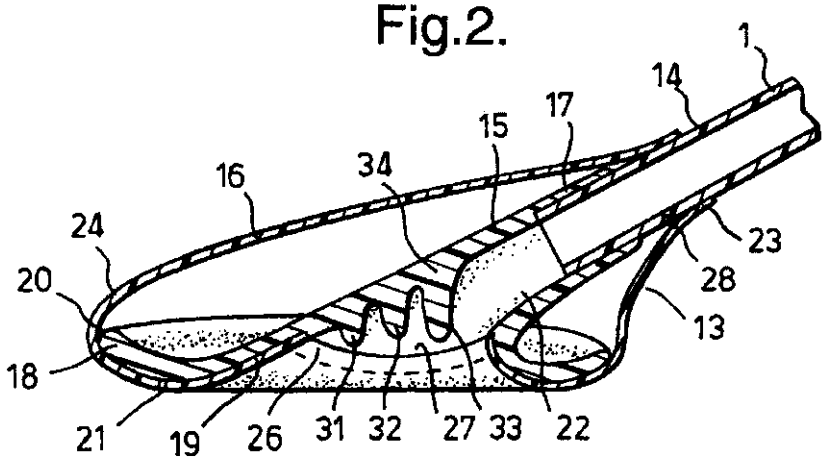


Fig.3.

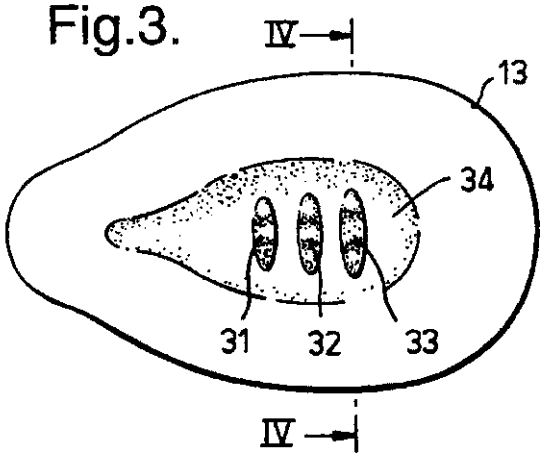


Fig.4.

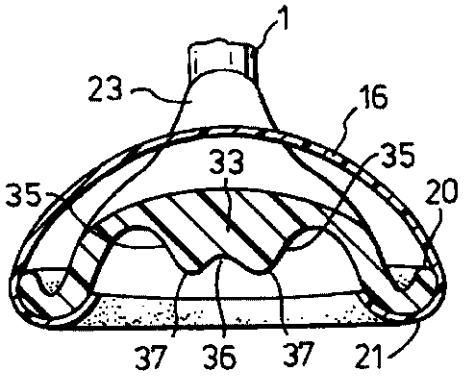


Fig.5.

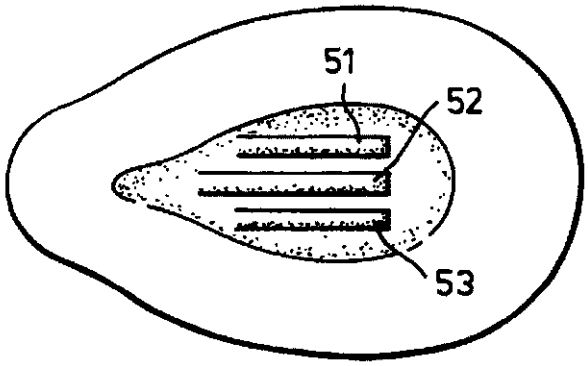


Fig.6.

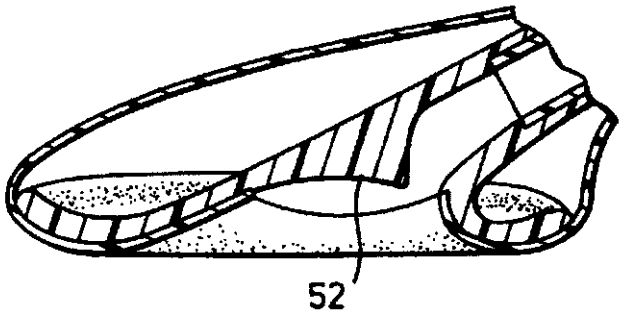
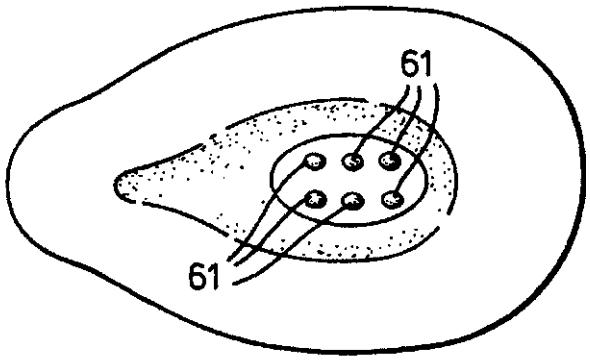


Fig.7.



LARYNGEAL MASK ASSEMBLIES

BACKGROUND OF THE INVENTION

This invention relates to laryngeal mask assemblies

It is common practice to use an airway known as a laryngeal mask for the administration of anaesthetic and ventilation gases to a patient. These airways comprise a tube with an inflatable mask or cuff at one end, the tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. Laryngeal masks are described in, for example, U.S. Pat. Nos. 5,355,879, 5,305, 743, 5,297,547, 5,282,464, GB 2267034, U.S. Pat. Nos. 5,249,571, 5,241,956, 5,303,697, GB 2249959, GB 2111394, EP 448878, U.S. Pat. No. 4,995,388, GB 2205499, GB 2128561 and GB 2298797.

Laryngeal masks have several advantages over endotracheal tubes, which are longer and seal with the trachea below the vocal folds. One problem with laryngeal mask airways, however, is that there is a risk that the epiglottis can enter the air passage through the airway during insertion, thereby causing a blockage. In GB-A-2205499 there is described a laryngeal mask having bars extending across the patient-end opening of the tube into the mask, to prevent the epiglottis from entering the opening.

SUMMARY OF THE PRESENT INVENTION

It is an object of the present invention to provide an improved laryngeal mask assembly.

According to the present invention there is provided a laryngeal mask assembly comprising a tube with a mask portion at its patient end, the tube opening into the center of the mask portion and the mask portion having a generally elliptical shape, the mask assembly having at least one member projecting down from the roof of the center of the mask portion, so as to deflect the epiglottis away from the opening of the tube during insertion of the assembly.

The at least one projecting member may be a rib extending laterally of the major axis of the elliptical shape of the mask portion. The lower end of each rib preferably has a concave profile with rounded projections at opposite ends. Alternatively, each projecting member may be a rib extending parallel to the major axis of the elliptical shape of the mask portion. The assembly may include three projecting members. In another arrangement, each projecting member may be a tooth with a rounded lower end. The mask portion preferably comprises a mount member attached with the tube and a cuff member attached with the mount member, the or each projecting member being molded with the mount member.

A laryngeal mask airway assembly according to the present invention, will now be described, by way of example, with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevation view of the assembly;

FIG. **2** is a sectional side elevation view of the patient end of the assembly to an enlarged scale;

FIG. **3** is a view from below of the patient end of the assembly;

FIG. **4** is a transverse sectional view along the line IV—IV of FIG. **3**;

FIG. **5** is a view from below of the patient end of an alternative assembly;

FIG. **6** is a sectional side elevation view of the patient end of the assembly shown in FIG. **5**; and

FIG. **7** is a view from below of another alternative assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to FIGS. **1** to **4**, the assembly comprises a bendable tube **1** of a plastics material, such as PVC, with a coupling **10** at its machine end **12**. The tube **1** is curved along its length and has a mask portion **13** at its patient end **14**.

The tube **1** is extruded with an inflation lumen **2** within its wall. The lumen **2** is connected towards the machine end of the assembly to an inflation line **3** with an inflation indicator and connector **4**. The opposite, patient end of the inflation lumen **2** opens into the mask portion **13**.

The mask portion **13** comprises a mount member **15** and a flexible bag member **16**. The mount member **15** is moulded from a bendable plastics material, such as PVC. The mount member **15** has a hollow cylindrical sleeve **17** at its rear end, in which the forward, patient end **14** of the tube **1** is inserted and joined. The forward, patient end **18** of the mount member **15** is of an inverted dish shape with a generally elliptical or egg-shaped outline and with a concave recess **19**. The peripheral edge **20** of the mount member **15** is curved rearwardly to form a convex peripheral forward surface **21** lying on a flat plane inclined at an angle of about 30° to the axis of the patient end of the tube **1**. The sleeve **17** has a bore **22** communicating with the passage through the tube **1**, at its rear end, and opening into the recess **19** at its forward end.

The bag member **16** is blow molded from a flexible, resilient plastics material, such as PVC, polyurethane, silicone, EVA, TPE, polyether block amide or the like. The bag **16** has a sock shape with an open ankle or neck portion **23** at its upper, rear end and an egg-shape lower, forward foot portion **24** shaped with the same general outline as the mount member **15**. The bag **16** encompasses the forward end of the assembly, enclosing the entirety of the mount **15** and having its neck **23** attached to the outside of the forward end **14** of the tube **1**, such as by solvent, adhesive or welding. The bag **16** is also attached to the concave recess **19** of the mount **15** along an annular band **26** extending around the opening of the bore **22**, to seal the bag material to the mount. A hole **27** in the bag **16** provides access to the bore **22** in the mount member **15**. The bag **16** provides an inflatable cuff at the forward end of the assembly and communicates with the inflation lumen **2** by means of an opening **28** cut through the outer surface of the tube **1** below the point where the bag is attached to the tube.

The mount member **15** also has, molded with it, an epiglottis deflector provided by three stiff ribs **31** to **33**, or similar members, projecting down from the roof **34** of the recess **19**. Each rib **31** to **33** extends laterally (that is, at right angles to the major axis of the elliptical shape of the mask portion) across only the central part of the mount member and has inclined sides **35** and a concave central region **36** forming two rounded projections **37**. The ribs are spaced from one another axially along the central part of the mount member **15** and project down about half the distance between the roof **34** and the forward surface **21**. The deflector acts to deflect the epiglottis during insertion of the mask assembly. The epiglottis is kept away from the roof **34** of the recess **19** in a region of the recess that is wider than the epiglottis so that there is always an air passage between

the epiglottis and the inside of the mask portion **13**. The gaps between adjacent ribs **31** to **33**, and the gaps between the ribs and the inside of the recess **19**, ensure that air is free to flow around the ribs into and out of the tube **1** but they are too small to allow the epiglottis to enter the bore **22** and block passage of air along the tube. The deflector allows a suction catheter, or the like to be inserted along the tube **1** and project from the mask portion.

Various alternative forms of deflector are possible. For example, as shown in FIGS. **5** and **6**, the deflector ribs **51** to **53** could be aligned longitudinally, that is parallel to the major axis of the elliptical shape of the mask portion. In such an arrangement, the forward end of the ribs is inclined smoothly from the roof of the recess.

Another arrangement is shown in FIG. **7** in which the deflector takes the form of a group of six downwardly-projecting teeth **61** arranged in two rows of three teeth. The lower end of the teeth **61** are rounded to make them atraumatic to the epiglottis, as it slides over the end of the teeth.

What I claim is:

1. A laryngeal mask assembly comprising: a tube with a forward, patient end and a rear, machine end; a mask portion at the patient end of said tube, said mask portion having a generally elliptical shape, and said tube opening into the center of said mask, said forwardly-projecting member being exposed for direct contact with the epiglottis so that the epiglottis is deflected away from the opening of said tube solely by the action of insertion of said assembly into a patient.

2. A laryngeal mask assembly according to claim **1**, wherein said projecting member is a rib extending laterally of a major axis of the elliptical shape of said mask portion.

3. A laryngeal mask assembly according to claim **2**, wherein said rib has a forward end with a concave profile and rounded projections at opposite ends.

4. A laryngeal mask assembly according to claim **1**, wherein said projecting member is a rib extending parallel to a major axis of the elliptical shape of said mask portion.

5. A laryngeal mask assembly according to claim **1**, including three said projecting members.

6. A laryngeal mask assembly according to claim **1**, wherein said projecting member is a tooth with a rounded lower end.

7. A laryngeal mask assembly according to claim **1**, wherein said mask portion comprises a mount member attached with said tube and a cuff member attached with said mount member, and wherein said projecting member is moulded with said mount member.

8. A laryngeal mask assembly comprising: a tube with a forward, patient end and a rear, machine end; a mask portion at said patient end of said tube, said tube opening into a center of said mask portion and said mask portion having a generally elliptical shape and a plurality of ribs projecting forwardly on said mask portion and extending parallel with and spaced apart from one another, said ribs being exposed for direct contact with the epiglottis, so as to form a gas passage between said ribs to said tube if a forward end of said ribs is engaged by the epiglottis during insertion of said assembly to a patient, and so that the epiglottis is deflected away from the opening of said tube solely by the action of insertion of said assembly into a patient.

9. A laryngeal mask assembly comprising: a tube with a forward , patient end and a rear, machine end; and a mask portion, said mask portion including a mount member of elliptical shape attached at the patient end of said tube, and a cuff member extending around a periphery of said mask portion, wherein said mount member has an opening communicating with the patient end of said tube and a plurality of forwardly-projecting members exposed to contact the epiglottis directly so that the epiglottis is deflected away from the opening into said tube solely by the action of insertion of the assembly and so that the forwardly-projecting members ensure a gas passage into said tube around said projecting members during insertion of said assembly into a patient.

10. A laryngeal mask assembly according to claim **9**, wherein said projecting members are parallel ribs.

11. A laryngeal mask assembly according to claim **9**, wherein said projecting members are teeth with rounded ends.

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